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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/227,749 | 01/08/1999 | BRIAN J. BALIN | 10062-1 | 7756 |

7590

07/11/2003

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EXAMINER

PESELEV, ELLI

ART UNIT

PAPER NUMBER

1623

DATE MAILED: 07/11/2003

35

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/227,749

Applicant(s)

BALIN ET AL.

Examiner

Elli Peselev

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 31-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 31-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 34.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Claims 31-38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

On page 17 of the specification it is stated that it has been discovered that *C. pneumoniae* infection of CNS is associated with Alzheimer's disease. However, applicants have failed to show that the treatment of said infection is effective in also treating Alzheimer's disease. The specification fails to show any correlation between the treatment of *C. pneumoniae* infection with antibiotics and the treatment of Alzheimer's disease.

Applicant's arguments filed May 29, 2003 have been considered but have not been found persuasive. The IDS submitted has been considered. However, the references submitted do not show any evidence that the treatment of *C. pneumoniae* infection is effective in treating Alzheimer's disease. Note that applicant admits on pages 1-3 of specification that Alzheimer's disease (AD) appears in two distinct forms and that signature neuropathology seen essentially in all AD patients includes the presence in the brain of neurofibrillary tangles and neuropil threads, and the presence of neuritic plaques. The genesis of these neuropathologies is poorly understood. Thus AD is a complicated disease for which there is no known effective treatment. Therefore, there is a good reason to doubt that antibiotics are effective in treating AD in the absence of any statistically significant data.

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Claims 31-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shor et al (U.S. Patent No. 5,424,187) in combination with Koskiniemi et al (Eur Neurol 1996; 36:160-163).

The instant claims are directed to a method of treating Alzheimer's disease which encompasses treating patients having C. pneumoniae infection.

Shor et al disclose the use of an antibiotic alone or in combination with an anti-inflammatory agent for the treatment of Chlamydia pneumoniae infection (column 2, lines 67-68 and column 3, lines 1-10) but do not disclose the treatment of said infection in central nervous system (CNS). However, since Koskiniemi et al disclose Chlamydia pneumoniae infections associated with CNS, a person having ordinary skill in the art at the time the instant invention was made would have been motivated to treat any disease which involves Chlamydia pneumoniae infection of CNS with an antibiotic or an antibiotic in combination with an anti-inflammatory agent.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elli Peselov whose telephone number is 703-308-4616. The examiner can normally be reached on weekdays 8.30 a.m. - 5.00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 703-308-4624. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.


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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Elli Peselev
July 10, 2003


ELLI PESELEV
PRIMARY EXAMINER
GROUP 1800